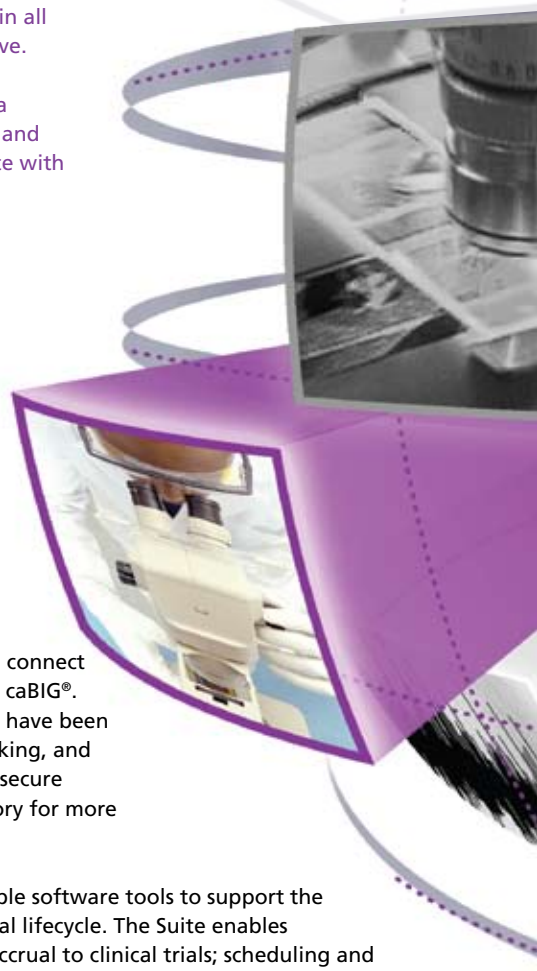
National Cancer Institute

caBIG® Clinical Trials Suite

The caBIG® Clinical Trials Suite facilitates electronic management of clinical trials and associated data and enables comprehensive sharing and integration of clinical research information—not only in cancer clinical trials, but in all clinical trials. The Suite provides four pathways to achieve this objective.

1. A set of software tools that can be adopted individually or as a bundle to support the execution of trials at one or more sites, and that contains tools to help existing systems adapt and integrate with the Suite
2. Guidance to adapt non-caBIG® systems to achieve compatibility with the caBIG® infrastructure
3. Components to integrate caBIG®-compatible tools with a caBIG®-compatible Clinical Data Management System (CDMS) selected by the organization
4. Components to facilitate the connection of caBIG®-compatible clinical trials systems to caGrid, the caBIG® grid infrastructure

Organizations can pursue these paths individually or in combination based on which solution best meets their needs.



The Suite supports the National Cancer Institute's overarching goal to connect the people, institutions, and data in the research community through caBIG®. This collection of tools and capabilities is one of three "bundles" that have been designed to support and streamline clinical trials, imaging, tissue banking, and integrative research, and to provide the materials needed to join the secure caBIG® data-sharing framework. Visit https://caBIG.nci.nih.gov/inventory for more detailed information and to access caBIG® resources.

The Suite is an integrated, stable, and secure collection of interoperable software tools to support the management of study participant information through the clinical trial lifecycle. The Suite enables management of tasks such as screening and registering patients for accrual to clinical trials; scheduling and tracking patient activities during the course of a study; integrating laboratory results with patient records; tracking and managing adverse events; and capturing, storing, analyzing, and routing clinical data in a consistent and meaningful manner.

In addition to software applications, the Suite also contains components to facilitate the electronic connection of the Suite to existing Clinical Data Management Systems and to the caBIG® infrastructure. These tools provide security features and access controls to ensure appropriate protection of human subject information and clinical research data.

Version 2.0 of the Suite has been enhanced to leverage the National Cancer Institute's services-based enterprise architecture. When users select study personnel and participating organizations, they are selecting from a curated global list. Through this process, errors, and inconsistencies are eliminated, and standards are enforced.

Features [Tools] included in the Suite

- Study participant registration [caBIG® Central Clinical Participant Registry (C3PR)]
- Participant schedule management [caBIG® Patient Study Calendar (PSC)]
- Access to clinical lab data from a virtual clinical data repository [caBIG® Lab Viewer]
- Adverse event management and reporting [caBIG® Adverse Event Reporting System (caAERS)]
- Clinical trials workflow integration [caBIG® Integration Hub (formerly caXchange)]
- Integration with Clinical Data Management Systems [caBIG® Clinical Connector (formerly C3D Connector)]
- caBIG®-compatibility infrastructure [caGrid]

U.S. Department of Health and Human Services

National Institutes of Health

caBIG® Clinical Trials Suite

Suite Tools	Description	Features	Features Continued	
caBIG® Central Clinical Participant Registry (C3PR)	Tracks registration of subjects on clinical trials	• Features a user-friendly dashboard interface • Features a workflow-based data entry wizard • Tracks clinical trial milestones (site initiation, informed consent, eligibility criteria, stratification, and treatment assignment) • Features an import option for importing study templates • Includes a companion protocol feature for tracking patients on multiple studies • Supports protocol amendments, backdated registrations, and re-consent	• Features e-mail and dashboard user notifications for study events • Enables error-free study personnel and organization management through the NCI Enterprise "Person" and "Organization" services • Generates parameterized study and registration reports • Enables NCI Cancer Centers Branch "Summary 3" Reporting • Facilitates integration and interoperability with other clinical systems in the caBIG® Clinical Trials Suite	C3PR
caBIG® Patient Study Calendar (PSC)	Enables clinical trial coordinators to schedule and manage treatment and care activities for each participant in a clinical trial	• Features a user-friendly dashboard interface • Creates templates to represent the events and activities within a study • Manages access to templates within a multi-site environment • Imports and exports study templates • Provides future and historical views of patient activities • Provides aggregate view of all patient activities for a coordinator • Manages changes to templates based on protocol amendments	• Manages re-consent of patients on a study • Generates reports using a flexible reporting interface • Receives AE notifications from the Adverse Event Reporting System (caAERS) and displays them in the patient calendar • Provides a link to Clinical Trial Objects Database System (CTODS) Lab Viewer from patient calendar • Receives patient registration from Cancer Central Clinical Participant Registry (C3PR)	PSC
caBIG® Lab Viewer	Enables users to search, display, and share clinical lab values from the CTODS Laboratory Database	• Features a user-friendly interface • Searches tabs to retrieve laboratory activity by study title or identifier, participant name, patient identifier, and range of dates • Filters lab results by lab test name, result (in/out of range), or date range • Exports lab results to .CSV, .XLS or .XML format • Selects and sends laboratory data sets to other applications in the caBIG® Clinical	Trials Suite through the caBIG® Integration Hub • Views site and investigator details for a study (validated through NCI Enterprise Services)	Lab Viewer
caBIG® Adverse Event Reporting System (caAERS)	Enables capture, management, and reporting of adverse events that occur during clinical trials	• Features a user-friendly dashboard interface • Features a workflow-based data entry wizard • Leverages an automated rules engine to facilitate compliance with regulatory, sponsor, protocol, and institution requirements • Generates study-level prompts for collection of solicited adverse events • Enables electronic report submission to the NCI Cancer Therapy Evaluation Program (CTEP) Adverse Event Expedited Reporting System (AdEERS)	• Facilitates use of customizable reports using NCI, FDA, EMEA and ICH-compliant report templates such as the MedWatch 3500A • Uses standards-based vocabularies and coding systems (e.g. CTCAE, MedDRA) • Populates forms by previously entered data to save time and minimize data entry errors • Features customizable adverse event routing, review, and submission notifications and workflow • Features an advanced search tab to query, analyze, and export nearly all data elements captured • Enables configurable and secure user access that can interface with enterprise single sign-on (SSO) • Facilitates integration and interoperability with other clinical systems in the caBIG® Clinical Trials Suite	caAERS
caBIG® Integration Hub (formerly caXchange)	Facilitates automatic capture of clinical laboratory data from laboratory systems and automatic translation and import to caBIG®-compatible clinical trials databases	• Leverages open-source standards based on Apache Servicemix to facilitate adherence to standards, vendor independence, and collaboration • Supports NCI's Build and Deployment Automation (BDA) framework to enable quick and easy deployments using a single command • Integrates Clinical Connector for generic integration to CDMS vendors such as Oracle Clinical and OpenClinica • Provides multiple connectivity options by supporting integration standards such as Web services, JEE, JMS, FTP, File, and Email • Provides an extensible and flexible ESB-based architecture using the JBI framework;	new JBI Components can be plugged in to extend and complement existing features • Simplifies integration of multiple disparate applications • Supports multiple XML formats including BRIDG and HL7 • Supports integration with caGrid and non-caGrid environments • Supports synchronous and asynchronous processing • Uses an abstraction layer to virtualize integration to NCI Enterprise Services • Provides reliable messaging, reliable transactions, and high availability, as well as message transformation and notification capabilities • Meets enterprise-class performance and reliability requirements • Provides a configurable mechanism for quickly, and easily adding and modifying integration scenarios using a set of configuration files	Integration Hub
caBIG® Clinical Connecter (formerly C3D)	Provides a conduit from the caBIG® Clinical Trials Suite to Clinical Data Management Systems (CDMS)	• Allows a patient registered in the caBIG® Central Clinical Participant Registry (C3PR) to be enrolled on the corresponding study in a caBIG®-compatible CDMS	• Allows the caBIG® Lab Viewer tool to transfer laboratory test results into the CDMS and populate the electronic Case Report Forms (eCRFs) • Allows study design metadata to be extracted from the CDMS along with context-related information	Clin. Connector
caGrid	Provides the services backbone for data and message exchange across all tools	• Connects all tools in the caBIG® Clinical Trials Suite • Ensures common identity and security management across applications • Enables message transport and routing and uniform data query and retrieval between systems	• Provides secure access, query, and retrieval of data across applications • Leverages federated security and identity management to support controlled access to systems • Includes a Globus-based data services grid and an index of registered services	caGrid

BUNDLE REQUIREMENTS

The caBIG® Clinical Trials Suite is a series of enterprise applications that must be installed following the minimum hardware and software configuration recommendations. Check the caBIG® tools Web page (https://cabig.nci.nih.gov/tools) for the most up-to-date information on the system requirements. This Suite is designed so that end users can access the applications from a standard internet web browser.

SUPPORTING SOFTWARE

- Apache Ant
- Apache Maven
- Apache Service Mix
- Apache Tomcat
- Java SE Development Kit (JDK)
- MySQL Database, Oracle Database or PostGreSQL Database
- caBIG®-compatible Clinical Data Management System (CDMS)

RESOURCES

- Overview of caBIG®: http://cabig.cancer.gov
- caBIG® Tool Inventory: https://cabig.nci.nih.gov/tools
- caBIG® Enterprise Support Network: https://cabig.nci.nih.gov/esn
- CTMS Knowledge Center: https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/
- caGrid information: https://cabig.nci.nih.gov/workspaces/Architecture/caGrid

For detailed information about caBIG® including available training programs and achieving caBIG® compatibility, please visit https://cabig.nci.nih.gov

For general information about getting connected with caBIG® visit https://cabig.nci.nih.gov/getting_connected

CONTACTS

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